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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,731	01/03/2001	Lawrence Loomis		1252

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EXAMINER
JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
1616	7

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/752,731	Applicant(s) LOOMIS ET AL.	
	Examin r D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-63,65-74 and 78-81* is/are rejected.

7)☒ Claim(s) *64 and 75-77* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 6, filed 3/24/06, wherein Applicant canceled claims 1-59 and claims 60-81 were added.

Note: Claims 60-81 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. Applicant's arguments with respect to claims 1-59 have been considered but are moot in view of the new ground(s) of rejection.

Note: The rejections were WITHDRAWN because Applicant canceled all of the previously pending claims and added new claims.

It is noted that all of the previous claims were canceled and new claims 60-81 were added which are product by process claims. Applicant is reminded that even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. Thus, the patentability of the product does not depend on its method of production. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even thought the prior art product was made by a different process. Hence, as it relates to the double patenting rejections below, if the product contained the same or obvious components as that appearing in Applicant's patented inventions, the products are considered to be the same even though the process of making the compositions are different.

Furthermore, it is duly noted that the term 'parenteral', using any standard medical dictionary (e.g., The Harper Collins Illustrated Medical Dictionary, pages 12 and 360) define the terms 'alimentary' and 'parenteral', respectively, as follows.

Alimentary: of or relating to food or nutrition.

Parenteral: situated outside the alimentary tract; taken into the body in a way other than through the alimentary canal, as by intravenous or intramuscular injection.

Thus, a parental composition is one that enters the body in a way other than or relating to food or nutrition.

NEW GROUNDS OF REJECTIONS

112 Second Paragraph Rejections

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 62 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 62, line 2: The claim as written is ambiguous because the period at the end of the sentence is missing. Thus, it is unclear whether Applicant intended to conclude the sentence or insert additional text. Please clarify.

Claim 78, lines 9-10: The claim as written is ambiguous because of the phrase 'in an amount effective to synergistically enhance the therapeutic effect". In particular, it

is unclear what Applicant intends by the phrase. What type of synergistic enhancement is Applicant claiming?

Note: It is duly noted that a similar rejection was made in the previous office action and Applicant responded by referring the Examiner to page 17, lines 15-16. The Examiner has review page 17, lines 15-16 and did not find a definition/explanation of the phrase.

Obviousness-type Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 60, 62, 65-72, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 13, 15, 20-23, 25, and 26 of U.S. Patent No. 5,997,862. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

7. Claims 60, 62, 65-74, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 13-15, 17, 20-25, 27, and 28 of U.S. Patent No. 6,017,528. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

8. Claims 60, 62, 63, 65-72, and 78-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-36 and 39-41 of U.S. Patent No. 6,056,955. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

9. Claims 60-63 and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,277,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

10. Claims 60 and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,097. Although the conflicting claims are not identical, they are not patentably

distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

11. Claims 60-63, 72, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6,432,444 of U.S. Patent No. 1-5. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

12. Claims 60, 62, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,399,098. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected

from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

13. Claims 60, 61, 63, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,406,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

14. Claims 60, 62, 65-74, and 79-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9, and 10 of U.S. Patent No. 6,423,299. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to parental compositions comprising at least on lyzing enzyme and a parental carrier. The claims differ in that the claims of the instant invention disclose that the enzyme(s) is selected from lytic, shuffled lytic, chimeric lytic, holing lytic, and combinations thereof wherein the patented invention reads generally on lyzing enzymes.

CLAIM OBJECTIONS

15. Claims 64 and 75-77 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

COMMENTS/NOTES

16. It should be noted that no prior art has been cited against claims 60-81. However, Applicant MUST address and overcome the double patenting and 112 rejections above. The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a composition as set forth in independent claim 60.

17. The documents cited in the double patenting rejections are not being mailed with this office action because the documents were submitted by Applicant on an information disclosure statement file 1/11/02, Paper No. 2, or listed on the notice of references cited by the Examiner and mailed with the office action on 2/24/02, Paper No. 3.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

June 3, 2003